Remarks/Arguments

In the Office Action, the Examiner required restriction to one of the following inventions under 35 U.S.C. §121:

I. Claims 1-16, drawn to an *ex-vivo* method for treating whole blood with CO, classified in class 435, subclass 2 and others.

II. Claims 17-28, drawn to a method for treating a platelet enriched fraction with CO, classified in class 435, subclass 2 and others.

III. Claims 29, 30 drawn to a method of treating a plasma fraction with CO, classified in class 424, subclass 539 and others.

IV. Claim 31, drawn to a method of inhibiting bacterial growth in platelet fraction by treating with CO, classified in class 604, subclass 5.02 and others.

V. Claim 32, drawn to a method for increasing storage stability of platelets comprising treating with CO and addition of a buffer, classified in class 435, subclass 2 and others.

VI. Claims 33-36, drawn to a method for treating either whole blood or platelets comprising treating with CO, and promoting exchange of CO with oxygen, classified in class 435, subclass 2 and others.

VII. Claims 37-40, drawn to a method of determining viability of platelets or whole blood after storage comprising determining the aggregation ability of the sample, classified in class 435, subclass 4 and others.

In the interests of clarity and to reduce the number of claims, Applicants have amended the claims to cancel claims 1-40 and to substitute therefore new claims 41-54, as set forth in the accompanying Preliminary Amendment. The new claims are directed to a method for ex-vivo treatment of a blood product, comprising treating a blood product with carbon monoxide. As described in more detail below, the generic term "blood product" as set forth in claims 41-54 encompasses whole blood and components selected from the group consisting of platelets, plasma, and blood stem cells.

In view of the cancellation of original claims 1-40 to which the Examiner applied a 7-way restriction requirement, and the presentation of new claims 41-54 (limited to one independent claim and 13 dependent claims) applicants respectfully request reconsideration and withdrawal of the restriction requirement. In the alternative, applicants request modification of the Restriction Requirement to allow prosecution of new claims 41-54 which encompasses claims in Groups I, II and III as designated by the Examiner in the present Application.

However, in the event that applicants are nevertheless required to elect one group for examination, Applicants hereby provisionally elect, with traverse, to prosecute the invention of Group II drawn to a method for treating a platelet-containing fraction of blood with CO. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right under 35 U.S.C. §121 to file one or more divisional applications directed to the non-elected subject matter during the pendency of this application, or an application claiming priority from this application. Furthermore, the cancellation of claimed subject matter does not constitute an admission by Applicants that the subject matter no longer claimed is not patentable. Applicants reserve the right to pursue all non-elected and cancelled subject matter in a continuing application or applications.

New claims 41-54 are directed to a method for ex-vivo treatment of a blood product, comprising treating a blood product with carbon monoxide. As defined in the specification on page 10, lines 14-15, a "blood product" is at least one of whole blood and a blood component. Support for the term "a blood component" may be found in Table I on page 2 of the specification, which Table lists blood components and their storage conditions. As set forth in claim 42, a "blood component" is selected from the group consisting of platelets, plasma, and blood stem cells. Support for the new claims may be found throughout the specification as originally filed, and no new subject matter is presented.

Under 34 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 80.201) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Applicants point out that MPEP §803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP §806.04 - §806.04(i)) or distinct (MPEP §806.05 - §806.05(i)).
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> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that Groups I, II and III represent distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of all groups would entail a "serious burden". See MPEP §803.

The Examiner justifies the requirement by stating that the inventions of Groups I-VII are patentably distinct from one another because they use different starting products, recite different steps, and have different end points. Second, the Examiner also argues that the inventions are independent and distinct from one another because they have acquired a separate status in the art and require independent searches, particularly literature searches, and require a different field of search.

Applicants respectfully submit that the Groups designated by the Examiner, and specifically Groups I, II and III, fail to define methods with starting products, steps, and end points so distinct as to warrant separate Examination and Search. All the methods of Groups I, II

and III are directed broadly to treatment of a blood product, whether it be whole blood or a blood component, with CO, and include the same method steps.

The inventions of all the various Groups, and particularly of Groups I, II and III are so closely related in the treatment of a blood product as defined in the specification with carbon monoxide, that a proper search of one blood product would, of necessity, include a search for other blood products. Due to the closeness of the subject matter, and the probably co-extensive or overlapping searches, Applicants respectfully Applicants submit that the Search and Examination of new claims 41-54 can be made without serious burden, and therefore the Examiner must examine these claims on the merits.

In the interest of economy, reconsideration and withdrawal of the Restriction Requirement are respectfully requested.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the Requirement for Restriction. An early action on the merits of the Claims is courteously solicited.

The Examiner is kindly requested to telephone the undersigned attorney of record for any reason that would advance the application to issue.

Respectfully submitted,

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